STANDARDS FOR PLATELET RICH PLASMA THERAPY

STANDARD

Department: Quality Improvement

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STANDARD – PLATELET RICH PLASMA THERAPY

INTRODUCTION

Platelet-rich plasma (PRP) is the name given to blood plasma with a high concentration of platelets that contains huge doses of bioactive proteins, such as growth factors, that are critical in the repair and regeneration of tissues. In order to extract these platelets an amount of 10 ml to 60 ml of blood is drawn from the patient and it immediately undergoes centrifugation, a process in which mixtures are separated using centripetal force. This process separates out red blood cells, which carry oxygen, and the platelet and the plasma. The platelets with the plasma have all of the healing agents. Once the separation is done, the platelet-rich plasma is extracted and can then be injected back into either the patient's injured area, or the area in the patient's body intended for therapy.

Growth factors can enhance tissue recovery and the special proteins also initiate blood vessel formation, bone regeneration and healing, connective tissue repair, and wound healing. There is little chance for rejection because the components used for treatment are extracted from a person's own body.

1. PURPOSE	
1.1	To define the minimum requirements including licensing and service specifications to ensure acceptable minimum levels of quality, performance, safety and reliability for provision of Platelet Rich Plasma (PRP) Therapy.
1.2	To evaluate and summarize the different applications of PRP and its applicability as well as advances and limitations of PRP therapy.
1.3	To ensure PRP therapy is delivered by appropriately licensed, qualified and trained healthcare professionals.

2. SCOPE OF APPLICATION	
2.1	The standard is applicable to all Dubai Healthcare City Authority Licensed Healthcare Operators which provide PRP therapy.
2.2	The Standard is applicable to all Dubai Healthcare City Authority Licensed Healthcare Professionals involved in the planning, delivering, monitoring of PRP therapy.

3. STANDARD	
3.1. LICENSURE REQUIREMENTS	
3.1.1	PRP therapy will only be provided by Dubai Healthcare City Authority licensed healthcare operators, holding a current and valid Clinical Operating Permit in accordance with the requirements of the Standards defined herein.

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3.1.2	Only Healthcare Operators with an approved Licensure and Clinical Operating Permit for Dermatology, Orthopedic Surgery, Plastic Surgery, Gynecology, Sports Medicine, Oral and Maxillofacial Surgery, and General Medicine Aesthetics may provide the Platelet Rich Plasma therapy.
3.1.3	Each Healthcare Operator providing PRP therapy must appoint appropriately qualified licensed healthcare professionals to deliver these services as required by this standard, the Dubai Outpatient Clinic Quality Standards or equivalent accreditation standards, DHCR Standards for Non-Surgical Cosmetic Procedures and other applicable DHCA regulations, standards and policies.
3.1.4	All licensed Healthcare Professionals will provide PRP therapy within their scope of practice and standards of proficiency for their licensed category.
3.1.5	Physicians who perform PRP injections must have knowledge of the diagnosis, standard treatments, benefits, risks, contraindications, methods of preparation and delivering it to the appropriate patient in the appropriate situation.
3.1.6	Physicians who perform PRP injections should be familiar with recent peer reviewed literature on PRP treatments for the diagnoses they are considering for PRP treatment.

3.2. OPERATIONAL REQUIREMENTS	
3.2.1	Each Healthcare Operator must have a documented process for determining appropriate staffing needs for the provision of PRP therapy.
3.2.2	Prior to commencing PRP therapy, each licensed Healthcare Operator must have in place written policies and procedures required for safe and effective practices in compliance with applicable regulations, policies and standards.
3.2.3	Each Healthcare Operator must implement standard operating procedures/ treatment protocols for PRP therapy at pre, post and follow up stages. In addition, the Healthcare Operator must ensure that the appropriate expertise and protocols are available and used for extraction, preparation, and activation of the plasma.
3.2.4	The Medical Director is responsible to grant privileges to physicians who will perform PRP therapy in accordance with their scope of practice and up to date required trainings and prior experience of performing PRP therapy.
3.2.5	All medical advertisement must comply with DHCR advertisement policy and MOHAP policy.

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3.2.6	All medical equipment used for PRP therapy including kits for Platelet Management shall be FDA, CE , IEC or MOHAP approved.
3.2.7	Preventive maintenance (PM) and annual electrical safety checks for all medical equipment must be carried out according to manufacturer's instructions.
3.2.8	PRP must be obtained using a separating device designed specifically for autologous blood.
3.2.9	Any specialist equipment used in the PRP therapy must include training of Healthcare Professionals as per manufacturer's recommendation.
3.2.10	Ensure appropriate privacy for patient and confidentiality and security of patient related information.
3.2.11	Each Healthcare Operator must implement policies and procedures for reporting any near miss or adverse incidents including, post-procedure infections, medication errors, adverse reactions, equipment failure etc.

3.3. Procedure Room Requirements	
3.3.1.	A clinical chair/ bed must be available with a reclining, multi-positioning back rest depending on the body area for the PRP therapy.
3.3.2.	Adequate work surfaces to allow space for the healthcare professionals to work ergonomically at the centrifuge as well as at the provision of the PRP therapy.
3.3.3.	Patient privacy and dignity must be respected and maintained at all times with appropriate curtains, shields or frosted glass protection.
3.3.4.	The lighting available must be sufficient.
3.3.5.	The clinic couch, trolley, and surfaces must be made up of material that can be appropriately cleaned and disinfected in between patients.
3.3.6.	The floor must be impervious and easy to clean.
3.3.7.	Dedicated handwashing facilities must be present in each treatment room providing PRP therapy.
3.3.8.	Sharps and clinical waste disposal must be provided within the treatment room designated for the PRP Therapy.

3.4. PATIENT MANAGEMENT- Pre PRP Therapy Procedure

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3.4.1.	PRP therapy must only be considered if there is a specific indication correlated with physical examination and /or as applicable confirmed with imaging studies such as x-ray, ultrasound, MRI, or CT scan prior to treatment as per the specialty.
3.4.2.	Appropriate patient education and discussion must take place with an informed consent signed prior to the initiation of the PRP procedure. Benefits, risks complications and side effects of treatment should be discussed and documented on the informed consent.
3.4.3.	Relative Contra-indications to the procedure such as critical thrombocytopenia, hyperfibrinogenemia, hemodynamic instability (collapse), sepsis , acute and chronic infections, chronic liver disease and anti-coagulation therapy (warfarin, heparin etc) are reviewed as applicable prior to initiation, are discussed with the patients.
3.4.4.	Additional contra indications are consistent use of NSAIDs within 48 hours of procedure , Corticosteroid injection at treatment site within 1 month , Systemic use of corticosteroids within 2 weeks , Tobacco use , Recent fever or illness , Cancer- especially hematopoietic or of bone , HGB < 10 g/dl , Platelet count < 105/ul.

3.5 PATIENT MANAGEMENT- Peri PRP Therapy Procedure	
3.5.1	All licensed healthcare professionals must wear their appropriate PPE to ensure the prevention of cross contamination during the procedure. Physicians and their assistants must ensure that they follow standard precautions and have training and skills in aseptic techniques.
3.5.2	Special attention must be paid to the sterility of the product, sterility/aseptic technique and specialized sterile kits should be used.
3.5.3	Movement of the plasma and associated additives must be minimal and be protected by labelling with the patient's full name and the Medical Records Number. Must be cross checked by minimum two individuals with their initials /signatures on the document.
3.5.4	Guidance technology appropriate to the body area treated may be used to ensure safe and appropriate injections i.e. CT, fluoroscopic, ultrasound, etc as per specialty.
3.5.5	Sterile single use needles, syringes and sterile gloves must be used with appropriate handling and disposal.
3.5.6	Prepare the site with appropriate antiseptic solution such as Betadine, Chlorhexidine specifically in PRP use in Musculoskeletal System.
3.5.7	To avoid unintentional activation of platelets, use large bore needles (>22) to draw the blood and re-inject PRP.

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3.5.8	The patient must remain in the room whilst the blood product, once withdrawn, undergoes the centrifuge procedure prior to reinjection of the final blood product. Minimal timeframe, preferable 15 minutes to 30 minutes should be observed between drawing the patient's blood, obtaining the PRP and injecting the PRP product into the patient.
3.5.9	Recognition, management and monitoring of any potential complications and Pain Management.

3.6 **PATIENT MANAGEMENT- Post PRP Therapy Procedure**	
3.6.1	Patient must be made to rest immediately after the procedure. Monitor for post-procedure complications. Assist patient if unable to ambulate post procedure specifically if related to PRP orthopedic procedures.
3.6.2	Patients must be provided with comprehensive health education and applicable exercise regimes especially related to PRP orthopedic procedures.
3.6.3	Patients must be informed on how to handle the area treated post procedure.
3.6.4	All patients must be informed and educated about the signs and symptoms of possible complications.
3.6.5	A follow up questionnaire is recommended to be used to monitor effects and achieve continuous improvement for patient outcomes.
3.6.6	All licensed Healthcare Professionals providing PRP therapy must document date, pre/post-procedure diagnosis, procedure title, performing physician w/wo assistants, brief indication of procedure, description of PRP preparation, description of procedure including guidance, and instruments.
3.6.7	Necessary follow-up and post procedure appointments with treating physician must be scheduled as appropriate.

4 DEFINITIONS	
4.1	**Clinical Operating Permit** means the authorization issued by the Registry of Companies to a healthcare operator allowing it to conduct one or more Clinical Activities.
4.2	**CE:** Stands for "European Conformity" marking. Which is the medical device manufacturer's claim that a product meets the essential requirements of all relevant European Medical Device Directives. The CE mark is a legal requirement to place a device on the market in the EU.

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4.3	**DHCA:** The Dubai Healthcare City Authority established under Article (4) of the Law, and comprises the Chairperson, the DHCC Board of Directors and the Executive Body.
4.4	**DHCR:** Dubai Healthcare City Authority Regulatory is the regulatory arm of Dubai Healthcare City Authority. An independent licensing and regulatory authority for all healthcare providers, medical, educational and other business licensed by DHCA.
4.5	**FDA :** The Food and Drug Administration is a federal agency of the United States Department of Health and Human Services, one of the United States federal executive departments
4.6	**IEC**: It stands for the International Electro technical Commission: An "organization that prepares and publishes international standards for all electrical, electronic and related technologies."
4.7	**Licensed Healthcare Operator**: a hospital, clinic, laboratory, pharmacy or other entity providing Healthcare Services in DHCC, holding a Clinical Operating Permit duly issued by the Registry of Companies in accordance with the Healthcare Operators Regulation and the applicable Rules, Standards and Policies.
4.8	**Licensed Healthcare Professional:** A natural person engaged in a Healthcare Profession holding a License duly issued by the Licensing Board in accordance with the Healthcare Professionals Regulation and the applicable Rules, Standards and Policies.
4.9	**MOHAP:** The Ministry of Health and Prevention is the ministry of the Government of United Arab Emirates which is responsible for the implementation of health care policy in all areas of technical, material, and coordination with the Ministries of State, and cooperation with the private sector in health locally and internationally.
4.10	**Platelet Rich Plasma Therapy (PRP)**: Platelet-rich plasma, also known as autologous conditioned plasma, is a concentrate of platelet-rich plasma protein derived from whole blood, centrifuged to remove red blood cells.

5	**REFERENCES**
5.1	http://www.cellmedicinesociety.org/attachments/206_ICMS%20-%20Guidelines%20for%20the%20use%20of%20Platelet%20Rich%20Plasma%20-%20Draft.pdf
5.2	DHA Platelet Rich Plasma Guideline 2014.pdf
5.3	Patient Instructions for PRP Final.pdf – New England Baptist Hospital ; PRP Injection Guidelines
5.4	PRP Guidelines –June 2018 Canada – Performance of Autologous Platelet Rich Plasma Therapy